UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

Hon. F. Kay Behm

TRUTEK CORP.,

Plaintiff,

v. Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.; ROBIN ROE 1 through 10, gender neutral fictitious names; and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY <u>JUDGMENT</u>

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A. Summary Judgment of Non-Infringement Should Be Granted¹

Faced with the fact that its experts provided contrary testimony demonstrating non-infringement, Trutek resorts to relying on marketing materials on BlueWillow's website. ECF 76, Ex. 1. Trutek mischaracterizes the contents and attributes a number of "admissions" that are not even present. Further, marketing documents alone are insufficient to prove infringement. *See Hilgraeve Corp. v. McAfee Assoc., Inc.*, 70 F. Supp. 2d 738, 756 (E.D. Mich. 1999), *aff'd in part, vacated in part on unrelated grounds*, 224 F.3d 1349 (Fed. Cir. 2000) (marketing documents "do not give rise to the inference that the accused product infringes" because the Court must "examine[] evidence concerning how the product *actually* operates."). Absent well-supported expert testimony and/or testing as to the actual operation of NanoBio® Protect, Trutek's argument based on marketing materials should be disregarded.

NanoBio® Protect Does Not Form a "Thin Film" Having "Adequate Impermeability": There is no dispute that NanoBio® Protect exists as individual droplets and does not form a continuous layer or barrier on the skin. ECF 76 at 5-6; ECF 59-3 at 222:24-224:1. While Trutek argues the film need not be "continuous," and even if it resembles Swiss cheese it still coats the skin as thin film (ECF 76 at 6), Trutek does not acknowledge Lemmo admitted element (b) requires a "barrier of

¹ Trutek does not contest BlueWillow's argument that summary judgment of no willful infringement is appropriate (ECF 59 at FN 1).

impermeability." ECF 40 at ¶¶32-33; ECF 59-3 at 141:2-142:8. Nor does Trutek address its claim construction arguments that the "thin film" is a solid, continuous, physical barrier. ECF 59 at 14; ECF 51-1. Not only does it strain credulity to imagine an impermeable film that resembles Swiss cheese, but Trutek cannot back away from its expert's opinions or the arguments it made during claim construction. *See Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 715 (Fed. Cir. 1998).

Trutek's other arguments premised on Exhibit 1 are equally unavailing. ECF 76 at 6-7, 11-12. While Trutek asserts the NanoBio® Protect droplets "surround and kill germs" and "persist on skin," nothing refers to "film," "adhesion," "cohesion," "impermeability" or "holding," each of which are required by element (b). ECF 76-1. Trutek ignores other facts, *e.g.*, NanoBio® Protect prevents germs by hydrating skin, not by creating an impermeable thin film. ECF 59 at 24. Lemmo conceded these different mechanisms of action (*id.*), yet Trutek does not respond to this point. Trutek's arguments are also unsupported by any testimony of Lemmo, who merely assumed NanoBio® Protect forms a film that exhibits "impermeability" because it does not drip out of the nose. ECF 59 at 11. Trutek points to no evidence of any material fact showing that NanoBio® Protect forms a thin film having adequate impermeability as required by element (b) of the asserted claims.

NanoBio® Protect Does Not Contain Sufficient Amount of BZK: Trutek again falls back on Exhibit 1 in the absence of any credible expert testimony. ECF

76 at 13. Exhibit 1 only states BZK works to "kill[] germs on contact" based on its long history as a skin antiseptic (ECF 76-1 at 2-3), but is silent as to whether the amount of BZK is sufficient to electrostatically inhibit, attract, hold, inactivate and render harmless those germs, as required by the claims (ECF 59 at 17-19).

Trutek also offers no credible explanation for Lemmo's testimony that the claimed technology will only function so long as the BZK concentration is within the ranges in the examples. ECF 59 at 18. Rather than rebut this evidence, Trutek improperly deflects the burden to BlueWillow. ECF 76 at 14 (arguing BlueWillow has not demonstrated 0.13% BZK would be ineffective). Trutek's assertion that there is no evidence that a lesser amount would be ineffective is incorrect as well. The patent explains (and Lemmo agreed) that varying the percentages of ingredients can impact potency, efficacy and consistency of the formulation. ECF 59 at 20.

Trutek's reliance on its own product development and testing of NanoBio® Protect is misplaced. ECF 76 at 14-15. The testing is inadmissible and irrelevant. ECF 59 at 21-22. If excluded, Trutek has no evidence other than Lemmo's conclusory opinion based on the presence of BZK in an amount lower than required by the claims. Yet, Trutek does not address that when rendering his opinions, Lemmo was not aware of the NanoBio® Protect ingredients, or his admission that the ingredients could impact the overall charge and even neutralize it altogether. ECF 59 at 22-24. Even if the testing is admissible, Trutek does not address the cases

showing it is improper to compare accused products to commercial embodiments for infringement, or the fact the testing is not even directed to the claim elements. ECF 59 at 22. Trutek points to no evidence of any material fact showing that NanoBio[®] Protect contains a sufficient amount of BZK to satisfy the claimed functions.

B. Summary Judgment of No Remedy Should Be Granted²

BlueWillow does not seek to be "rewarded" for its allegedly infringing acts.

Rather, it would be "unjust and manifestly unfair" to allow Trutek to conduct a trial by ambush by disclosing its damages and marking evidence for the first time at trial.

Trutek Has Not Met Its Burden to Prove Damages: Trutek once again tries to shift blame for its failures to BlueWillow. ECF 76 at 17-20. BlueWillow was unwilling to disclose confidential financial data without a protective order; Trutek *never* filed the order. ECF 76 at 18. Nevertheless, BlueWillow provided sales data on a confidential basis in June 2022 in furtherance of mediation. ECF 46 at 1. Despite having the data for a year, Trutek has not supplemented or disclosed its damages theory or any evidence it intends to rely on.³ While BlueWillow disagrees expert testimony is unnecessary, the fact that Trutek decided to not retain an expert and

² Trutek did not respond to BlueWillow's arguments concerning a permanent injunction or request for jury trial. Nor is Trutek "entitled to damages as a matter of law" under § 284 and Rule 54(c). *See* 35 U.S.C § 287 ("Limitation on damages"); ECF 39 at 14-16 (§ 284 does not absolve patentee of burden of proof on damages). ³ Contrary to Trutek's assertion, the mediator informed BlueWillow that Trutek did not allow him to share Trutek's lost profits estimate, and Trutek cites no evidence proving this information was ever provided to BlueWillow.

present fact testimony instead (ECF 76 at 19-20) does not excuse its failure to comply with pre-trial disclosure obligations.

To recover lost profits, Trutek must show (1) demand for patented product; (2) absence of acceptable, noninfringing substitutes; (3) manufacturing capability to exploit demand; and (4) profit that would have been made. *Presidio Components*, Inc. v. Am. Tech. Ceramics Corp., 875 F.3d 1369, 1380 (Fed. Cir. 2017). Each factor relies on evidence in Trutek's control, independent of BlueWillow sales.⁴ To recover a reasonable royalty, Trutek must "present competent evidence regarding how the factfinder should perform the reasonable royalty calculation." *Unicom Monitoring*, LLC v. Cencom, Inc., No. CIV.A 06-1166 (MLC), 2013 WL 1704300, at *8 (D.N.J. Apr. 19, 2013). "[T]he factfinder needs either clear guidance from an expert about how to apply complex calculations or simple factual proofs about what this patentee has previously accepted in factually analogous licensing situations." *Id.* Not only has Trutek not disclosed its claimed damages, it hasn't disclosed any evidence it intends to introduce at trial, and indeed, does not attempt to argue that it has.

Trutek Has Not Met Its Burden to Prove Pre-Suit Damages: Trutek cites no cases establishing entitlement to pre-suit damages. ECF 76 at 16. It also ignores

⁴ While the total amount of lost profits depends in part on units sold by BlueWillow, there is no dispute that the amount of profit to be applied to each purported lost sale is solely within Trutek's possession, independent of BlueWillow's sales volumes.

that it is *Trutek's* burden to establish compliance, not BlueWillow's. ECF 76 at 21.⁵ The only "evidence" Trutek relies on is two statements from experts, based on purchase of a single product, hardly enough to demonstrate "substantially consistent and continuous" compliance through the requisite period. *See* ECF 76 at 22; ECF 59 at 29. Nor does Trutek even allege that licensees of the '802 patent have properly marked their products. ECF 59 at 29 n. 2; *Clancy Sys. Int'l, Inc. v. Symbol Techs., Inc.*, 953 F. Supp. 1170, 1171-75 (D. Colo. 1997) (summary judgment limiting damages when plaintiff offered no evidence either licensee had marked its products).

C. Summary Judgment of Invalidity Should Be Granted

Rather than focusing on the claim language, Trutek confusingly identifies 10 "attributes" it alleges Baker '476 must disclose. ECF 76 at 26. Regardless, Haidri concedes Baker '476 discloses elements (a) and (c) of the asserted claims. 6 ECF 59 at 36. As to element (b), Trutek relies on meritless attorney argument that runs counter to its own infringement theory. Trutek assumes for infringement that the NanoBio® Protect composition has sufficient adhesion and cohesion because to be useful, it can't drip out of the nose (ECF 76 at 5), while complaining this feature is not expressly disclosed in Baker '476 (ECF 76 at 28). Trutek cannot have it both

⁵ BlueWillow met its burden to provide notice of unmarked products. ECF 59-3, ¶11.

⁶ Trutek acknowledges element (a), referred to as attribute 5, is inherent in Baker '476, but argues it was not "recognized." ECF 76 at 29. An inherent disclosure does not need to be recognized, or utilized, at the time of the disclosure to be anticipatory. *Perricone v Medicis Pharm. Corp.*, 432 F.3d 1368, 1377-78 (Fed. Cir. 2005).

ways, and its assertion that NanoBio® Protect was not developed until 2020 (ECF 76 at 37-38) is irrelevant. Baker '476 discloses the same composition as NanoBio® Protect. ECF 59 at 37. Amiji compared Baker '476 to the patent claims, explaining how if NanoBio® Protect satisfies the claims under Trutek's interpretation, the Baker '476 composition inherently does so as well. ECF 59 at 37-39; *01 Communique Lab.*, *Inc. v. Citrix Sys.*, 889 F.3d 735, 742-43 (Fed. Cir. 2018). While Trutek asserts the NanoBio® Protect formulation may have been adjusted (ECF 76 at 37), it provides no evidence to support its claim and Amiji's testimony is unrebutted on this point.⁷

For the reasons stated herein, summary judgment should be granted in favor of BlueWillow on (1) non-infringement, (2) remedy and (3) invalidity.

Dated: June 15, 2023 Respectfully submitted,

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⁷ While Trutek argues one example of disagreement by Lemmo (ECF 76 at 36-37), Amiji presented other reasons why element (b) is inherently taught by Baker '476, including by virtue of the fact that Baker '476 discloses the same composition as NanoBio® Protect. Trutek cites no evidence or facts in dispute on this point.

CERTIFICATE OF SERVICE

I hereby certify that, on June 15, 2023, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

/s/ Nicholas J. Ellis